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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/789,046	02/25/2004	Mao-Kuei Chang		8339

7590  
Mao-Kuei Chang  
P.O. Box 55-846  
Taipei, 104  
TAIWAN

08/20/2007

EXAMINER
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RAMDHANIE, BOBBY

ART UNIT	PAPER NUMBER
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1709

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/789,046

Applicant(s)

CHANG, MAO-KUEI

Examiner

Bobby Ramdhanie, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 25 February 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3, 6, 8-15, 17, 18 and 20 is/are rejected.
- 7) ☒ Claim(s) 4, 5, 7, 16 and 19 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 02/25/2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- 1) ☒ Certified copies of the priority documents have been received.
  - 2) ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date: \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Claim Rejections - 35 USC § 102*

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-3, 6, & 8-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Levy (US6030582). Levy teaches a fecal examination apparatus comprising a collector means (Figure 1) having suction or pumping portion formed thereon (Figure 1 Item number B); and a container base formed as a bottle for filling a fecal sample or specimen and reagent therein (Figure 1; Item number 10); said collector means removably mounted on and in said container base and having a quantitative chamber formed in said collector means (Figure 1 Item numbers P, R, S, & T), whereby upon operation of said suction means, a fecal sample including liquid or loose stool will be sucked inwardly into said collector means and will be collected or filled into said container base for examination (Figure 1).

3. For Claim 2, Levy teaches a fecal examination apparatus according to Claim 1, wherein said collector means includes a hollow stem (Figure 1 Item number S) having the suction portion formed on said stem (Figure 1 Item number B), a sleeve member removably secured in the container base (Figure 1 Item number 18) and slidably engaging the hollow stem and having a cap (Figure 1 Item number 14) formed on a top

of said sleeve member for capping the container base (Figure 1 Item number 10).

Examiner takes the position that the septum is a sleeve member.

4. For Claim 3, Levy teaches a fecal examination apparatus according to Claim 2, wherein said hollow stem (Figure 1 Item number S) includes a plunger (Figure 1 Item number T) formed on a bottom of said stem, having an aperture (Figure 1 Item number E) formed through the plunger allowing air into the inlet or outlet through said aperture when operating the suction portion of the collector means (Figure 1 Item number P). Examiner takes the position that Figure 1 Item number T can be considered a plunger.

5. For Claim 6, Levy teaches a fecal examination apparatus according to Claim 1 wherein said container base includes a container portion (Figure 1 Item number 10) formed as a transparent bottle defining an interior in the containing portion for filling the fecal specimen and test reagent therein, and a cover (Figure 1 Item number 14) detachably secured on an upper portion of the container portion having a holding cylindrical portion (Figure 1 Item number 18) of the container protruding upwardly from the cover to be engaged with a cap on the sleeve member for removably mounting the collector means including the hollow stem and the sleeve member on the container base (Figures 1, 2, & 3). Examiner takes the position that the septum can also acts as the holding cylindrical portion.

6. For Claim 8, Levy teaches a fecal examination apparatus according to Claim 6, wherein said holding cylindrical portion is connected with the cover with a flexible shoulder portion, allowing universal movement of the collector means within the container base (Figures 1, 2, & 3 Item numbers 14 and 18).

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7. For Claim 9, Levy teaches a fecal examination apparatus according to Claim 1 wherein said container base includes a base portion formed on a bottom on the container to be stably held on a surface (Figures 1 & 4 Item number 10).

8. For Claim 10, Levy teaches a fecal examination apparatus according to Claim 9, wherein said base portion includes a quality control testing platform formed on the base portion for checking the quality of a test reagent (Figure 1 Item number 10). Examiner takes the position that the outer surface of the container can be used as a test platform to check the quality of the reagent.

***Claim Rejections - 35 USC § 103***

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Levy in view of Mitchell et al (US4563332). Regarding Claim 3, Levy teaches a fecal

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examination apparatus according to Claim 2, wherein said hollow stem (Figure 1 Item number S) includes a plunger formed on a bottom of said stem (Figure 1 Item number T), having an aperture formed through the plunger allowing air into the inlet or outlet through said aperture when operating the suction portion of the collector means (Figure 1 Item number E). Levy does not teach that the physical shape of the plunger to be other than the lower shaft portion of the pipette. Mitchell et al teaches another shape the plunger may have (Figure 1 Item number 42). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Levy with Mitchell et al because this shape would greatly prevent the amount of fecal or stool remains from reaching the bulb in an abrupt or forceful suction event.

12. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Levy in view of Chang (US5066463). Regarding Claim 11, Levy in combination with Chang, teach all of the claim limitations according to Claim 10. Levy does not teach a fecal examination apparatus according to Claim 10 wherein said testing platform includes a first test pool; and a second test pool for dripping a respective test reagent therein. Chang teaches these features. Chang teaches a fecal examination apparatus according to Claim 10 wherein said testing platform includes a first test pool; and a second test pool for dripping a respective test reagent therein (Figure 5 & Column 3 lines 15-24 & Column 4 lines 45-46). It would have been obvious to one skilled in the art at the time the invention was made to modify Levy with Chang because, according to Chang, this would allow for the analysis of high and low sensitivity of blood occult samples to be performed (Abstract and Column 3 lines 15-24).

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13. Claims 12-15, 17, & 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Levy in view of Chang (US4849173). Regarding Claim 12, Levy teaches all of the claim limitations of Claim 1. Levy does not teach a fecal examination apparatus according to Claim 1, wherein said container base includes a filling port formed in the container base for filling a test reagent into the container portion when a fecal specimen is collected and stirred therein; and a vent formed in the container base for venting air outwardly when filling a specimen and reagent into the container base. Chang teaches these features. Chang teaches a hole for directing air into the container base (Column 2 lines 6-7, & lines 54-57). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Levy with Chang because as Chang suggests, this hole would allow for smooth discharge of a fecal solution (Column 2 lines 54-57). Examiner takes the position that the filling port and vent port are considered the same.

14. For Claim 13, Levy and Chang teach all of the claim limitations of Claim 12. Levy does not teach a fecal examination apparatus according to Claim 12, wherein said container base includes a plug formed on the container base for closing the filling port and the vent. Chang teaches these features. Chang teaches a fecal examination apparatus according to Claim 12, wherein said container base includes a plug formed on the container base for closing the filling port and the vent (Figure 1 & Column 2 lines 52-53). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Levy with Chang because as Chang suggests, this hole would allow for smooth discharge of a fecal solution (Column 2 lines 54-57). Examiner

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takes the position that the collector means is part of the cover, which in turn, is part of the container base. The collector means has a hole that is considered the same as the filling port and can double as the vent port.

15. For Claim 14, Levy teaches all of the claim limitations of Claim 1 including said container base, which includes a container portion; a cover detachably secured to an upper portion of the container portion for removably mounting the collector means in the container portion. Levy does not teach a fecal examination apparatus wherein said base container includes a base portion secured to a bottom portion of the container portion; having a hopper portion formed in a lower portion of the base portion for receiving a fecal solution which is formed by mixing a fecal sample and a reagent as drained from the container portion; and having a drain tube protruding downwardly from the hopper portion to be connected to a centrifugal test tube for centrifugal examination. Chang teaches these features. Chang teaches a fecal examination apparatus wherein said base container includes a base portion secured to a bottom portion of the container portion (Figure 1 Item number 20); having a hopper portion formed in a lower portion of the base portion for receiving a fecal solution which is formed by mixing a fecal sample and a reagent as drained from the container portion (Figure 1 Item number 21); and having a drain tube protruding downwardly from the hopper portion to be connected to a centrifugal test tube for centrifugal examination (Figure 1 Item number 211 & Column 3 lines 18-24). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Levy with Chang because according to Chang this would



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allow the remaining fecal solution to be subject to further laboratory tests such as microscopic inspection for parasites (Column 3 lines 18-24).

16. For Claim 15, Levy in combination with Chang, teach all the claim limitations of Claim 14. Levy does not teach a fecal examination apparatus according to Claim 14, wherein said container base includes a filter formed between the container portion and the hopper portion of the base portion for filtering suspension matter or dirt in the fecal solution. Chang teaches this feature. Chang teaches a fecal examination apparatus according to Claim 14, wherein said container base includes a filter formed between the container portion and the hopper portion of the base portion for filtering suspension matter or dirt in the fecal solution (Column 3 lines 18-24). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Levy with Chang because according to Chang this would allow the remaining fecal solution to be subject to further laboratory tests such as microscopic inspection for parasites (Column 3 lines 18-24).

17. For Claim 17, Levy in combination with Chang, teach all claim limitations of Claim 14. Levy does not teach a fecal examination apparatus according to Claim 14, wherein said container portion further includes: a valve moveably secured in a lower periphery of the container portion for normally sealing a drain opening formed in a bottom plate of the container portion. Chang teaches this feature. Chang teaches a fecal examination apparatus according to Claim 14, wherein said container portion further includes: a valve moveably secured in a lower periphery of the container portion for normally sealing a drain opening formed in a bottom plate of the container portion (Column 2

lines 23-31). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Levy with Chang because according to Chang this would allow the remaining fecal solution to be subject to further laboratory tests such as microscopic inspection for parasites (Column 3 lines 18-24).

**18.** For Claim 18, Levy in combination with Chang, teach all claim limitations of Claim 17. Levy does not teach a fecal examination apparatus according to Claim 17, wherein said valve includes a lever protruding outwardly through a notch cut in the lower periphery of the container portion, having a device formed on the container portion for normally receiving the lever of the valve, whereby upon withdrawal or operation of the lever of the valve to open the opening, the fecal solution will be drained into the base portion to be received by a test tube connected to the base portion. Chang teaches these features. Chang teaches a fecal examination apparatus according to Claim 17, wherein said valve includes a lever protruding outwardly through a notch cut in the lower periphery of the container portion, having a device formed on the container portion for normally receiving the lever of the valve, whereby upon withdrawal or operation of the lever of the valve to open the opening (Column 2 lines 23-31 & Column 3 lines 18-24), the fecal solution will be drained into the base portion to be received by a test tube connected to the base portion (Column 3 lines 18-24). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Levy with Chang because according to Chang this would allow the remaining fecal solution to be subject to further laboratory tests such as microscopic inspection for parasites (Column 3 lines 18-24).

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19. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Levy and Chang (US4849173), and in further view of Chang (US5066463). Regarding Claim 20, Levy in combination with Chang (US4849173), teaches all the claim limitations of Claim 14. Levy does not teach a fecal examination apparatus according to Claim 14 wherein said container base includes a quality control testing platform on the container portion including a first test pool and a second test pool respectively formed on a rim portion of the container portion for checking the effectiveness of two test reagents respectively added to the test pools. Chang (US5066463) teaches this feature. Chang teaches a fecal examination apparatus according to Claim 14 wherein said container base includes a quality control testing platform on the container portion including a first test pool and a second test pool respectively formed on a rim portion of the container portion for checking the effectiveness of two test reagents respectively added to the test pools (Figure 1; Item numbers 25, 26, 27, and Example C Column 4 lines 15-25). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Levy and Chang (US4849173) with Chang (US5066463) because according to Chang (US5066463) this would provide an instrument for examining fecal sample with multiple choices and purposes (Column 1 lines 30-46).

### ***Claim Objections***

20. Claim 3 is objected to because of the following informalities: The Claim is an incomplete sentence. The words ""into the" need to be inserted between "air" and "inlet". Appropriate correction is required.

***Allowable Subject Matter***

21. Claims 4, 5, 7, 16, and 19 are objected to as being dependent upon rejected base claims, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The following is a statement of reasons for the indication of allowable subject matter: Regarding Claim 4, Claim 4 teaches a fecal examination apparatus according to Claim 2 wherein said hollow stem has a pair of positioning keys. The prior art of record does not teach nor disclose a fecal examination apparatus with positioning keys on said stem.

22. For Claim 5, Claim 5 teaches a fecal examination apparatus according to Claim 4, which includes a sleeve member with a stopping portion. The prior art of record does not teach nor disclose this feature.

23. For Claim 7, Claim 7 teaches a fecal examination apparatus according to Claim 6 wherein said holding cylindrical portion is downwardly connected with a tapered conical portion. The prior art of record does not teach nor disclose this feature.

24. For Claim 16, Claim 16 teaches a fecal examination apparatus wherein said container portion includes a plurality of retaining rods formed on the bottom portion of the container portion. The prior art of record does not teach nor disclose this feature.

25. For Claim 19, Claim 19 teaches a fecal examination apparatus wherein said container portion includes a test port that is laid on the filter and positioned below the test port. The prior art of record does not teach nor disclose this feature.

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**Conclusion**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bobby Ramdhanie, Ph.D. whose telephone number is 571-2702-3240. The examiner can normally be reached on Mon-Fri 8-5 (Alt Fri off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Walter Griffin can be reached on 571-272-1447. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

BR

Melvin Hayes  
*[Signature]*  
Primary Examiner  
AU1734